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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,720	12/01/2000	Steven K. H. Foung	2002850-0009	5311

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EXAMINER	
WORTMAN, DONNA C	
ART UNIT	PAPER NUMBER
1648	13

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,720	FOUNG ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-23,25-32,66,67,70 and 92-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-23,25-32,66,67,70 and 92-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's election of Group II, claims 1, 3-23, 25-32, 66, 67 and 70, drawn to antibodies specific for HCV E2 epitopes, corresponding pharmaceutical applications, and corresponding cell lines, in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The preliminary amendment filed February 11, 2002, as Paper No. 9 has been entered. The newly presented claims in that amendment were renumbered as claims 75-91 in accordance with Rule 126. The preliminary amendment filed April 30, 2002, as Paper No. 12 has also been entered. By that amendment, claims 2, 24, 33-65, 68, 69 and 71-74 as originally filed were canceled, and the claims that had been renumbered as claims 75-91 were also canceled. The claims newly presented in Paper No. 12 have been renumbered as claims 92-100 in accordance with Rule 126. Claims 1, 3-23, 25-32, 66, 67, 70, and 92-100, insofar as drawn to antibodies specific for HCV E2 epitopes, corresponding pharmaceutical applications, and corresponding cell lines are pending and under examination.

The file record indicates that an Information Disclosure Statement was filed on May 24, 2001; however, this paper cannot be located. If Applicant wishes to replace the IDS at the time of the response to this action, the replacement will be entered and treated as if filed on May 24, 2001.

Claim 10 is objected to because of the following informalities:

In line 1, "conformation" should read "conformational."

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7, 25-27, 30, 93, 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7 are indefinite because claim 4 recite "the dissociation constant (K_D) ..." while claims 5-7 recite "the binding constant (K_D) ...". If these two constants, dissociation and binding, are intended to represent the same thing, as might be thought since they are symbolically represented in the same way, K_D, it is suggested that consistent terminology be adopted throughout the claims. If they are not the same, clarification is needed.

Claims 25, 26, and 27 are indefinite because each depends from canceled claim 2.

Claims 30 and 99 are indefinite in reciting "treating a patient infected with HCV" comprising "providing a patient infected with HCV or susceptible to HCV infection." It is not clear whether the method is intended to be a method for treating or a method for preventing HCV infection.

Claim 32 is indefinite in reciting "the step of administering the antibody comprises administering more than one different antibody." It is not clear whether the additional antibody or antibodies must also be an antibody within the scope of claim 1, or whether it or they can be any "different" antibody.

Claim 66 is indefinite because the basis for identifying a patient as a candidate for administration of a treatment is not specified, nor is the nature of the treatment for which the patient is a candidate specified or made clear.

Claim 70 is indefinite in reciting "wherein the step of administering comprises ..." without antecedent in claim 66 which recites only "providing," "measuring," and "identifying."

Claim 93 is confusing in reciting "the combination results in ...", since it would seem that binding of the combination, and not merely the presence of the combination, is required. Claim 93 is further confusing because it appears to encompass the embodiment in which two or more antibodies can be directed to a single epitope, yet it requires that the combination of antibodies will result in increased binding to that same epitope.

Claim 94 is indefinite in reciting "the increased binding ... is greater than 100% relative to the binding of a single antibody." It is not clear how the binding is to be measured, and it is not clear whether "greater than 100%" encompasses any amount of increase at all, such as 100.1%, e.g., of the binding of the single antibody, or whether it requires that the binding increase, by whatever measure, be at least two-fold, i.e., a greater than 100% increase, compared to the binding of a single antibody. If the claim is intended to encompass any amount of increase, then there is a question as to whether or not claim 94 further limits the subject matter of claim 93.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4-7 are drawn to an antibody directed to a conformational epitope of a protein of hepatitis C virus wherein the dissociation constant, K_D, of the antibody for its epitope has specific values ranging from "less than 10^{-7} M" to "less than 10^{-10} M." While an original claim may be taken to provide written description, the specification does not appear to teach or describe the production and/or selection of antibodies to conformational epitopes of hepatitis C virus with particular values for binding constants, or characterized according to their binding constants for their epitopes, such that one would recognize that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 12, 13, 95, 96, and 97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is evident that the antibodies designated CBH-2, -4D, -4B, -4G, -5, -7, -8C, -8E, -9, -11, and -17 are required in order to practice the invention as claimed since each is specifically recited in one or more of claims 12, 13, 95, 96, and 97. Since the production of a specific monoclonal antibody is a very rare event, one of skill in the art would not have a reasonable expectation for success in making exactly these

antibodies again. Consequently, biological deposit of these materials is required as set forth in 37 CFR 1.801-1.809.

Claims 29, 30-32, 66, 67, 70, and 98-100 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 29 is drawn to a pharmaceutical composition comprising an antibody directed to a conformational epitope of a protein of hepatitis C virus. Claims 30-32 are drawn to methods of treating a patient exposed to or infected with hepatitis C virus by administering at least the antibody of claim 1. Claims 66, 67 and 70 are drawn to a method of treating a previously identified candidate patient (claim 66) by administering "an antibody" (claim 67) which may be an anti-HCV monoclonal antibody that binds an epitope wherein the binding of the monoclonal antibody to the epitope is not inhibited by the patient's serum (claim 70). Claim 98-100 are drawn to pharmaceutical compositions and treatment methods using antibody combinations. The specification at page 91 shows that some HCV-infected patient sera have antibodies that compete for binding to the epitopes bound by monoclonal antibodies CBH-2 and CBH-7 and that patients with relatively lower titers of those antibodies belonged to a group with higher median viral load. The specification states: "Thus, most HCV infected individuals are characterized by low levels of serum antibodies with putative neutralization activity," and "Therapeutic use of HCV-neutralizing human monoclonal antibodies, such as CBH-2 and CBH-7, has the potential to be of value in these individuals." The claims are not limited to

administration of CBH-2 and CBH-7, however. These two monoclonal antibodies were categorized as "neutralizing" antibodies in an *in vitro* neutralization of binding assay. Claims 29 and 30-32 require only that the antibody to be administered be directed to a conformational epitope of a protein of Hepatitis C virus; claims 67 and 70 require that serum of the patient to whom the antibodies are to be administered be first tested for antibodies that bind to the same epitope as an anti-HCV monoclonal antibody; claim 67 recites the administration of "an antibody" of no particular specificity, and claim 70 recites the administration of an antibody directed to an epitope to which no antibodies There is no indication that administration of such antibodies would have any beneficial effect. The state of the art at or about the time the invention was made and the level of predictability in the field are appropriately considered in determining enablement. In this regard, Burioni et al. (Hepatology 28(3):810-814, 1998, cited on PTO 892, attached), states at page 813, second column: "At present, the NOB [neutralization of binding] appears to be a possible measure of antiviral activity. However, the correlation between the NOB activity and true virus neutralization activity remains to be proven." Even if the claims were to be limited to administration of CBH-2 and CBH-7, the specification does not provide a basis for correlating results of the *in vitro* assay with obtaining a beneficial result, either protective or therapeutic, in a patient to whom the antibodies as claimed are administered.

Claims 93 and 94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the combination of the antibodies CBH-7 and CBH 4-G, wherein the binding of one antibody to a conformational epitope results in

increased binding of the other antibody to a second conformational epitope, does not reasonably provide enablement for any and all combinations of antibodies wherein the combination results in increased binding of the antibodies to one or more conformational HCV E2 epitopes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. While the specification discloses selection of a variety of antibodies to HCV E2 conformational epitopes, only one very specific pair has the claimed properties, indicating that this property is rarely found, and the specification does not provide guidance for increasing the yield of what appear to be a synergistic pair of antibodies. Lacking such guidance, it would require undue experimentation for one of skill in the art to make a pair of antibodies with the required property.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-23, 25-29, and 92-98 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5 and 59 of copending Application No. 09/430489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to antibodies that are either the same as, or have the same binding specificity as, the antibodies of claims 3-5 and 59 of Application No. 09/430489 and thus would have been obvious over those antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 15-17, 19, 21, 22, 25, 26, 29, 92, and 98 are rejected under 35 U.S.C. 102(a) as being anticipated by Da Silva Cardoso et al. (Journal of Medical of Virology 55:28-34, May 1998), cited on PTO 892, attached, and cited in the specification of parent application 09/187057, filed 11/5/98, as prior art. Da Silva Cardoso et al. disclose several human monoclonal antibodies to conformational epitopes on HCV E2, compositions comprising the antibodies that are not distinguished from the compositions of claim 29 and claim 98, and EBV-transformed human B cells that produce them, thus anticipating the subject matter of the cited claims.

Claims 1, 3, 14, 15, 22, 23, 25, 26, 28, 29, 92, and 98 are rejected under 35 U.S.C. 102(a) as being anticipated by Burioni et al. cited above and cited by applicant in the specification of both the instant application and parent application 09/187057 as prior art. Claims 1, 3, 15, 22, 23, 25, 26, 28, 29, 92 and 98 enjoy the benefit of the filing date of 09/187057, viz., 11/5/98. Burioni discloses human monoclonal recombinant antibody Fab fragments specific for HCV E2 conformational epitopes (page 812, bottom column 1), compositions comprising the antibodies that are not distinguished from the compositions of claims 29 and 98, and the production of the Fab molecules in an *E. coli* system, thus anticipating the claimed subject matter.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Burioni et al., cited above. Claim 4 is drawn to an antibody directed to a conformational epitope of a protein of Hepatitis C virus that has a dissociation constant for its epitope of less than 10-7 M. Since this claim receives the effective filing date of the instant application, 12/01/00, Burioni is available under 35 U.S.C. 102(b). Burioni discloses, in the last sentence of the paragraph bridging pages 811-812, "The inhibition constants shown in Fig. 3 are implying monomer Fab-antigen binding constant on the order of 10^7 to 10^8 mol/L^{-1}." Considering the indefinite nature of claim 4 and the lack of explanation as to how the K_D of instant antibodies was actually determined, as discussed above, Burioni is deemed to anticipate the subject matter of claim 4.

Claims 1, 3, 4, 5, 14, 15, 22, 23, 25, 26, 28, 29, 92, and 98 are rejected under 35 U.S.C. 102(b) as anticipated by WO 97/40167, Persson et al., published 10/30/97, cited on PTO 892, attached. Persson et al. disclose recombinant human monoclonal

antibodies specific for conformational HCV E2 epitopes that have Kd's of as little as .6 nM, i.e., less than 10^{-8} M (see, e.g., Table III).

Claims 1, 15-19, 21, 22, 25, 26, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Mondelli et al. (Journal of Virology 68(8): 4829-4836, 1994), cited on PTO 892, attached. Mondelli et al. disclose a human monoclonal antibody to a conformational epitope on HCV NS3, compositions comprising the antibody that are not distinguished from the composition of claim 29, and the EBV-transformed human B cell line that produces it, thus anticipating the subject matter of the cited claims.

Claims 1, 3, 15, 18, 19, 20, 25, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Deleersnyder et al. (Journal of Virology 71(1):697-704, January 1997), cited on PTO 892, attached. Deleersnyder et al. disclose a murine monoclonal antibody to a conformational epitope of HCV E2, compositions comprising the antibody that are not distinguished from the composition of claim 29, and a hybridoma cell line that produces it, thus anticipating the subject matter of the cited claims.

Claims 1, 3, 15-19, 21, 22, 25, 26, 28, 29, 92, and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Habersetzer et al., Hepatology 24(4), Pt. 2, 381A, Abstract 1020, 1996, cited on PTO 892, attached. Habersetzer et al. disclose several human monoclonal antibodies to conformational epitopes on HCV E2, compositions comprising the antibodies that are not distinguished from the compositions of claim 29 and claim 98, and EBV-transformed human B cells that produce them, thus anticipating the subject matter of the cited claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-13 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either one of Da Silva Cardoso et al. or Burioni et al. as cited above. The antibodies of Da Silva Cardoso and of Burioni et al. reasonably appear to be the same as, or only slightly different from, the claimed antibodies in terms of their binding specificity since they were obtained from HCV infected individuals as were Applicant's, they were selected for binding specificity in the same manner as were Applicant's, they bind to conformational epitopes on the HCV E2 protein as do Applicant's, and they give the same or similar results in neutralization of binding assays as do Applicant's antibodies; consequently, in the absence of factual

evidence to the contrary, they reasonably appear to be the same as or only slightly different from the antibodies of claims 8-13.

Claims 8-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of Persson et al., Deleersnyder et al., or Habersetzer et al. The antibodies of Persson et al., Deleersnyder et al., and Habersetzer et al. reasonably appear to be the same as, or only slightly different from, the claimed antibodies since they were obtained from HCV infected individuals, they were selected in the same manner, they bind to conformational epitopes on the HCV E2 protein, and they give the same or similar results in neutralization of binding assays; thus, in the absence of factual evidence to the contrary, they reasonably appear to be the same as or only slightly different from the antibodies of claims 8-13.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burioni et al., cited above and applied to claim 1, and cited by applicant in the specification of both the instant application and parent application 09/187057 as prior art. Claims 5-7 are drawn to antibodies directed to a conformational epitope of a protein of Hepatitis C virus that have particular binding constants for their epitope or epitopes. Since these claims receive the effective filing date of the instant application, 12/01/00, Burioni is available under 35 U.S.C. 102(b). Burioni discloses human monoclonal recombinant Fab fragments specific for HCV E2 conformational epitopes, discloses monomer Fab-antigen binding constant on the order of 10^7 to 10^8 mol/L^{-1} , and suggests selecting high-affinity human monoclonal antibodies (see, e.g., first sentence of

paragraph bridging pages 810-811). It would have been obvious to one of ordinary skill in the art to have selected high-affinity monoclonal antibodies to conformational HCV epitopes as recited in claims 5-7 because Burioni teaches the selection of high-affinity human monoclonal antibodies from random combinatorial libraries.

Claim 27 is free of the prior art of record since there would be no need to humanize the prior art human monoclonal antibodies and, in the case of the murine monoclonal antibody of Deleersnyder et al., there is no motivation to humanize Deleersnyder's antibody in the absence of a reasonable expectation for success in using it for human therapeutic purposes.

Claims 30-32, 66, 67, 70, 99 and 100 are free of the prior art of record which does not teach or suggest that the antibodies as claimed can be used for human therapeutic purposes without undue experimentation and with a reasonable expectation for success.

Claims 93 and 94 are free of the prior art of record which does not teach or suggest combination of two or more antibodies to one or more conformational epitopes of HCV E2 protein, wherein the combination results in increased binding to one or more conformational epitopes of HCV E2.

Claims 95-97 would be allowable if the claims were rewritten to be limited to the specifically recited monoclonal antibodies, the biological deposit conditions were met, and the obviousness double patenting issue were to be settled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is

703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
September 8, 2002